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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/165,546    10/02/98    ALEXANDER    K    LUD5466.4-JE

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HM12/0104

EXAMINER

DIBRINO, M

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

01/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/165,546

Applicant(s)

Alexander et al.

Examiner  
Mariann DiBrino

Group Art Unit  
1644



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 1-73 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claims 1-73 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice to Comply with Sequence Rules

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5, 9, 10, 14, 15 and 55-60, drawn to an isolated polypeptide and composition thereof, classified in Class 530, subclass 326.

II. Claim 6, drawn to a CTL, classified in Class 435, subclass 325.

III. Claims 7, 8 and 63 drawn to complexes of HLA and polypeptide, classified in Class 530, subclasses 350.

IV. Claims 11-13, 17, 18 and 61, 62, 64 and 65, drawn to nucleic acid, vector and host cell or cell expressing nucleic acid product, classified in Class 536, subclass 23.1 and Class 435, subclasses 252.3 and 320.1.

V. Claim 16, drawn to a kit comprising nucleic acids, classified in Class 536, subclass 23.5.

VI. Claims 19-24, drawn to a method of stimulating Th cells in vitro, classified in Class 424, subclass 185.1.

VII. Claims 25-31, drawn to a method of simulating Th cells in vivo comprising administering a polypeptide or composition thereof, classified in Class 424, subclass 185.1.

VIII. Claims 32-34 and 41, drawn to a method of stimulating Th cells in vivo comprising administering a cell, classified in Class 424, subclass 93.1.

IX. Claim 35, drawn to a method of treating cancer in a subject using an antibody, classified in Class 424, subclass 130.1.

X. Claims 36-38 and 40, drawn to a method for preventing cancer using a composition comprising a polypeptide, classified in Class 424, subclass 185.1.

XI. Claim 39, drawn to a method for preventing cancer in a subject comprising administering an expression vector comprising a nucleic acid encoding a polypeptide, classified in Class 514, subclass 44.

XII. Claim 42, 43 and 47-52, drawn to a method for screening for cancer comprising assaying for protein complexes, classified in Class 435, subclass 7.24.

XIII. Claims 42, 43 and 47-54, drawn to a method for screening for cancer comprising assaying for cells, classified in Class 435, subclass 7.1.

XIV. Claims 44-46, drawn to a method for diagnosing cancer in a subject comprising assaying for immunoreactive cells using a cell line transfected with an isolated nucleic acid encoding a polypeptide, classified in Class 435, subclasses 6 and 7.21.

XV. Claims 68 and 69, drawn to a method for stimulating CTL comprising contacting a CTL with a peptide and an HLA-A2 molecule, classified in Class 514, subclass 8.

XVI. Claims 71-73, drawn to a method for stimulating CTL comprising administering to a subject a peptide to an HLA-A2 positive cell, classified in Class 514, subclass 15.

XVII. Claims 68 and 70, drawn to a method for stimulating CTL comprising administering a cell to a subject, classified in Class 424, subclass 93.7.

XVIII. Claims 66 and 67, drawn to a non-proliferative cell which expresses a complex of HLA/peptide on its surface, and composition thereof, classified in Class 435, subclass 252.3 and Class 424, subclass 93.7, respectively.

4. Inventions I, II, III, IV, V and XVIII are different products.

Polypeptides (Group I), CTL (cytotoxic T cells, Group II), complexes of HLA (proteins) and polypeptide (Group III), nucleic acid encoding a polypeptide (and a vector and host cell comprising said nucleic acid, Group IV), a kit comprising separate nucleic acids which encode for a polypeptide or an HLA molecule and a non-proliferative cell (Group XVIII) are distinct because their structures and modes of action are different.

The products of Groups I, II, III, IV and V are clearly differ from each other in that they are structurally and functionally distinct products and are made by different methods. The products of Groups I and III, although both comprise proteins, the proteins are structurally unique proteins (i.e. a polypeptide vs complexes of an HLA molecule and a polypeptide). Moreover, the proteins of Groups I and III are unique from the nucleic acid, vector and host of

Group IV, the nucleic acid of Group V and the CTL of Group II. Nucleic acids are made of a different compositions than proteins are (nucleic acids vs. amino acids). The nucleic acid of group IV or V can be used as a probe to detect a gene or as a template to make a protein. The DNA, vector and host as well as the method of making a protein using DNA will be examined together because the host and vector are expressly used for the purpose of protein expression. The CTL of Group II is distinct from the host cell of Group IV because they are different cell types.

5. Inventions VI - XVII are different methods.

These inventions require different ingredients, process steps and endpoints.

For example, the methods of Groups VII, VIII, IX, X, XI, XV XVI and XVII are in vivo methods of stimulating T cells or treatment or prevention of cancer, whereas the methods of Groups VI XII, XIII and XIV are in vitro methods for stimulating Th cells in vitro or for screening for/ diagnosing cancer. In addition, the methods of Groups VII and VIII are methods for stimulating Th in vivo comprising administering a polypeptide or a cell, respectively, whereas, the methods of Groups IX, X and XI are methods of treating cancer by administering an antibody, preventing cancer by administering a composition comprising a polypeptide, or preventing cancer by administering an expression vector comprising a nucleic acid encoding a polypeptide, respectively. The method of Group XVII is a method for stimulating proliferation of CTL using a non-proliferative cell. The method of Group XII is a method for screening for cancer comprising assaying for protein complexes, whereas the method of Group XIII is a method for screening for cancer comprising assaying for cells. The method of Group XIV is a method for diagnosing cancer in a subject comprising assaying for immunoreactive cells using a cell line transfected with an isolated nucleic acid encoding a polypeptide. The method of Group XIV uses the said transfected cell line, whereas the method of Group XIII can use cell lines which are pulsed with the appropriate polypeptide rather than transfected with a nucleic acid encoding said polypeptide.

6. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an immunogen for the elicitation of antibodies.

7. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

(M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for the production of antibodies or in immunoaffinity purification.

8. Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for the production of antibodies.

9. Inventions I and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for the production of antibodies.

10. Inventions IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for the production of a polypeptide.

11. Inventions II and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for adoptive transfer.

12. Inventions III and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an immunogen in vivo.

13. Inventions IV and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for an immunogen.

14. Inventions XVIII and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as for stimulating CTL in vitro or for assay of CTL.

15. Inventions IV and VII are not related as products and a method of use. Therefore, they are novel and unobvious in view of each other and are patentably distinct.

16. Inventions I-V and Invention IX are not related products and a method of use. Therefore, they are novel and unobvious in view of each other and are patentably distinct.

17. Inventions II and XV are not related product and a method of use. The CTL of Group II is specific for an HLA-DR53 binding peptide that is one of SEQ ID NO: 8-10, whereas the method of Group XV uses a CTL specific for a complex of HLA-DR53 and SEQ ID NO: 7. Therefore, they are novel and unobvious in view of each other and are patentably distinct.

18. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I - XVI is not required for any other group from Groups I - XVI and Groups I - XVI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

19. **If Applicant elects Group I,** Applicant is further required to (1) **elect a specific polypeptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 12, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These polypeptides are distinct because their structures are different.

20. **If Applicant elects Group II,** Applicant is further required to (1) **elect a specific CTL specific for a complex of HLA-DR53 and a specific polypeptide, i.e., a CTL specific for a complex of HLA-DR53 and a specific SEQ ID NO**, such as for example, Seq ID NO: 12, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These CTL are distinct because they recognize different peptides with different structures.

21. **If Applicant elects Group III,** Applicant is further required to (1) **elect a specific complex of HLA-DR53 with a specific polypeptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 12, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

22. **If Applicant elects Group IV,** Applicant is further required to (1) **elect a specific nucleic acid molecule encoding a specific polypeptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 12, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

23. **If Applicant elects Group V,** Applicant is further required to (1) **elect a specific kit comprising a specific nucleic acid encoding a specific polypeptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 12, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These kits are distinct because they comprise nucleic acids with different structures.



24. **If Applicant elects Group VI**, Applicant is further required to (1) **elect a specific method comprising administering a specific polypeptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use polypeptides that are distinct because their structures are different.

25. **If Applicant elects Group VII**, Applicant is further required to (1) **elect a specific method comprising administering a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use peptides that are distinct because their structures are different.

26. **If Applicant elects Group VIII**, Applicant is further required to (1) **elect a specific method comprising administering a specific cell transfected with a specific nucleic acid that encodes a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use cells that comprise a nucleic acid that encodes distinct peptides having distinct structures and physicochemical properties.

27. **If Applicant elects Group IX**, Applicant is further required to (1) **elect a specific method comprising administering an antibody that binds a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use antibodies which recognize distinct peptides having distinct structures and physicochemical properties, and said antibodies also have distinct structures.

28. **If Applicant elects Group X**, Applicant is further required to (1) **elect a specific method comprising administering a specific composition comprising a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use specific compositions comprising specific peptides which have distinct structures and physicochemical properties.

29. **If Applicant elects Group XI**, Applicant is further required to (1) **elect a specific method comprising administering a specific expression vector comprising a specific nucleic acid encoding a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use vectors which comprise nucleic acids encoding distinct peptides having distinct structures and physicochemical properties.

30. **If Applicant elects Group XII**, Applicant is further required to (1) **elect a specific method comprising administering a specific expression vector comprising a specific nucleic acid encoding a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use vectors which comprise nucleic acids encoding distinct peptides having distinct structures and physicochemical properties.

31. **If Applicant elects Group XIII**, Applicant is further required to (1) **elect a specific method comprising assaying for a specific complex comprising a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they assay for distinct peptides having distinct structures and physicochemical properties using an agent/antibody having a distinct structure and physicochemical properties.

32. **If Applicant elects Group XIV**, Applicant is further required to (1) **elect a specific method for diagnosing comprising contacting an immune reactive cell containing sample to a cell line transfected with a specific nucleic acid molecule which encodes a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use different cells comprising distinct nucleic acids having different structures and which encode distinct peptides having distinct structures and physicochemical properties.

33. **If Applicant elects Group XV**, Applicant is further required to (1) **elect a specific method comprising contacting a specific CTL which recognizes complexes of HLA-A2 with a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use CTL which recognize complexes of HLA-A2 with distinct peptides having distinct structures and physicochemical properties.

34. **If Applicant elects Group XVI**, Applicant is further required to (1) **elect a specific method comprising administering a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use distinct peptides having distinct structures and physicochemical properties.

35. **If Applicant elects Group XVII**, Applicant is further required to (1) **elect a specific method comprising administering a specific cell expressing a specific complex comprising a specific HLA molecule and a specific peptide, i.e., a specific SEQ ID NO**, such as for example, Seq ID NO: 8, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they use distinct cells expressing HLA/peptide complexes, wherein the HLA molecules and peptides have distinct structures and physicochemical properties.

36. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

37. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

38. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

M.P.E.P. § 809.02(a).

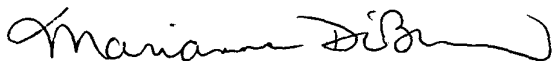
39. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

40. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.


41. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Marianne DiBrino, Ph.D.  
Patent Examiner  
Group 1640  
Technology Center 1600  
December 22, 1999



CHRISTINA Y. CHAN  
SUPERVISOR, PATENT EXAMINER  
GROUP 1600 1640

Application No.: 09/165,516

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING  
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: \_\_\_\_\_

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For Patent/In software help, call (703) 308-6856

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**

COPY FOR [ ] File [x] Applicant